UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

COCHLEAR LTD., Plaintiff, v. OTICON MEDICAL AB, and OTICON MEDICAL, LLC Defendants.	Civil Action No. 3:18-cv-06684-BRM-DEA **OPINION**

MARTINOTTI, DISTRICT JUDGE

Before this Court is an Order to Show Cause (ECF No. 3) why Plaintiff Cochlear Ltd. ("Cochlear" or "Plaintiff") should not be granted a preliminary injunction enjoining Defendants Oticon AB and Oticon Medical, LLC (collectively, "Oticon" or "Defendants") "from infringing Cochlear's recently issued U.S. Patent No. 9,838,807 (the "'807 Patent") by selling, offering for sale, and/or importing Oticon's Ponto BHX implant." (Pl.'s Mot. for a Preliminary Injunction (ECF No. 3-1) at 1.) Pursuant to Federal Rule of Civil Procedure 78(a), the Court heard oral argument on October 16, 2018. Upon reviewing the papers submitted by the parties and considering the arguments of counsel, for the reasons set forth below, Plaintiff's application is **DENIED**.

I. BACKGROUND

Cochlear is an Australian Corporation that develops and manufactures bone anchored hearing systems. (Pl.'s Complaint (ECF No. 1 ¶¶ 1-2).) Cochlear sells its products in the United States through its subsidiary Cochlear Americas, a Colorado corporation. (Mendel Decl. (ECF No. 3-4 ¶ 2).) Oticon Medical AB, a Swedish corporation, and Oticon Medical, LLC, a New Jersey

corporation, are both subsidiaries of William Demant Holdings A/S ("WDH"), an affiliate of the William Demant Group, a hearing healthcare company with a presence in over 130 countries. (Olsen Decl. (ECF No. 37-1 ¶ 1, 16).) On December 5, 2017, the United States Patent and Trademark Office issued the '807 Patent to Cochlear for its "Bone Anchor Fixture for a Medical Prothesis." (Compl. Ex. A (ECF No. 1-1).) On April 13, 2018, Cochlear filed a Complaint alleging that Oticon infringed the '807 Patent with the manufacture and sale of its Ponto BHX Implants. (ECF No. 1.) On the same date, Cochlear filed a Motion for a Preliminary Injunction by Order to Show Cause, pursuant to Federal Rule of Civil Procedure 65, seeking to enjoin and restrain Oticon from "making, using, offering to sell, and selling within the United States, and importing into the United States, the Ponto BHX Implant or any colorable imitations thereof." (ECF No. 3-2.)

II. LEGAL STANDARD

"Preliminary injunctive relief is an 'extraordinary remedy, which should be granted only in limited circumstances.'" *Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 210 (3d Cir. 2014) (quoting *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586 (3d Cir. 2002)). "A plaintiff seeking a preliminary injunction must establish that he is [1] likely to succeed on the merits, [2] that he [or she] is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his [or her] favor, and [4] that an injunction is in the public interest." *Ferring*, 765 F.3d at 210 (quoting *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008)). The failure to establish any of the four elements "renders a preliminary injunction inappropriate." *Ferring*, 765 F.3d at 210 (quoting *NutraSweet Co. v. Vit-Mar Enters., Inc.*, 176 F.3d 151, 153 (3d Cir. 1999)). "The movant bears the burden of showing that these four factors weigh in favor of granting the

injunction." *Ferring*, 765 F.3d at 210 (citing *Opticians Ass'n of Am. v. Indep. Opticians of Am.*, 920 F.2d 187, 192 (3d Cir. 1990)).

III. FACTUAL BACKGROUND

A. The Bone Conduction Hearing Systems

Both Cochlear and Oticon manufacture and sell bone conduction hearing systems, also known as bone anchored hearing systems. (ECF No. 3-4 ¶ 3; ECF No. 37-1 ¶ 1.) These devices conduct sound wave vibrations from a sound processor through a patient's skull bones to bypass a damaged outer and middle ear and send sound directly to the inner ear. (ECF No. 3-4 ¶ 3.) Cochlear distributes two types of implantable bone conduction hearing systems: Baha® Connect ("Baha Connect") and Baha® Attract ("Baha Attract"). (ECF No. 3-4 ¶ 4.) The Baha Connect, which is at issue in this litigation, uses an implant secured to the skull and connected to a skin penetrating abutment attaching to a sound processor that picks up sound and generates the vibrations transmitted through the bone to the inner ear. (ECF No. 3-4 ¶ 5.)

In 2009, Oticon launched its "Ponto" bone anchored hearing system. (ECF No. 37-1 ¶ 3.) The Ponto has three basic components: the BHX implant which sits in the bone behind the ear; the abutment which connects to the implant and extends outwardly through the skin; and the sound processor which attaches to the abutment above the skin level. (*Id.*) Oticon's Ponto and Cochlear's Baha Connect are direct market competitors, as the Baha Connect also incorporates the same three-part structure. (Popelka Decl. (ECF No. 38 ¶ 20).)

The Ponto BHX Implant, which is at issue in this litigation, is the "third generation" of Oticon's skull implant, designed for use with the Ponto abutment and sound processors. (ECF No. 37-1 ¶¶ 19-20.) The Ponto BHX Implant uses a laser ablation technology to modify the surface of the implant's titanium screw where it comes into contact with the bone so as to improve its

"osseointegration." (*Id.*) Osseointegration is the process by which new bone binds with the implant surface and the implant exhibits mechanical stability allowing the load-carrying implant to conduct hearing. (ECF No. 3-4 ¶ 9.) Improved osseointegration promotes implant stability and allows the implant to be loaded to the living bone sooner. (ECF No. 3-4 ¶ 9; ECF No. 37-1 ¶¶ 9-10.) As is evident from the diagrams of the Ponto BHX Implant and the Cochlear BI300 Implant, the implant in the Baha Connect, the Ponto BHX Implant has a single screw thread of constant pitch, whereas the Cochlear BI300 Implant has two distinct screw threads of differing pitches. (ECF No. 37-2, Ex. 5; ECF No. 3-4 ¶ 8.)

B. The '807 Patent and Cochlear's Claims

On December 5, 2017, the United States Patent and Trademark Office issued Cochlear the '807 Patent, titled "Bone Anchor Fixture for a Medical Prothesis," which expires on September 27, 2027. (ECF No. 1-1.) The '807 Patent discloses features for a bone conduction implant, including a tapered portion (labeled as 108), a flange for providing a stop (labeled as 103), and a circumferential groove between the flange and the threads (labeled as 117). (ECF No. 1-1, figs. 1 and 2; Rentschler Decl. (ECF No. 3-5, Ex. B).)

Cochlear asserts Oticon infringed only two independent claims in the '807 Patent: claims 1 and 8. (ECF No. 1-1). Every other '807 Patent claim upon which Cochlear alleges an infringement necessarily depend upon or are incorporated within claim 1 and/or claim 8. Pursuant to claim 1 of the '807 Patent, Cochlear claims:

> An anchoring fixture for anchoring a prosthesis to a skull bone comprising: a screw thread apparatus including a screw thread having a varying outer diameter; a flange configured to function as a stop for the anchoring fixture adapted to rest on top of the bone when the anchoring fixture is implanted into the bone; and a circumferential groove located, with respect to a side of the flange, on the anchoring fixture on a threaded side of the anchoring fixture, wherein the anchoring fixture is configured for anchoring a hearing

> prosthesis component to the skull bone at a location behind an external ear so that sound is transmitted from the hearing prosthesis via the skull bone to the cochlea.

(ECF No. 1-1 at 8.)

Pursuant to claim 8 of the '807 Patent, Cochlear claims:

> A bone fixture configured to anchor to bone, comprising: a threaded tapered portion, wherein a maximum width of the bone fixture is about the same as a height of the bone fixture; a flange configured to function as a stop for the bone fixture adapted to rest on top of the bone when the bone fixture is implanted into the bone; and a circumferential groove located, with respect to a side of the flange, on the bone fixture on a threaded side of the bone fixture, wherein the bone fixture is configured to anchor a hearing aid prothesis to a skull bone at a location behind an external ear of a recipient so that sound is transmitted from the hearing prosthesis via the skull bone to the cochlea.

(*Id.*)

C. The Licensing Agreement

Cochlear and Oticon are parties to various licensing and cross-licensing agreements that convey rights to import and sell certain implants in the United States. (ECF No. 37-1 ¶¶ 16-18.) Specifically, in 2009, Cochlear entered into a "Cross Patent License Agreement" (the "2009 License") with WDH, an affiliate of the William Demant Group and Oticon's parent company. (ECF No. 37-2, Ex. 7.) The 2009 License conveys to WDH and its affiliates a right to be free of suit by Cochlear for selling any of several specified Cochlear patents. The 2009 License states, in pertinent part:

> 2.2 Cochlear grants to WDH a world-wide, non-exclusive, non-transferable, fully paid-up license to make, use, sell, offer for sale or have made for use or sale, only by WDH and its Affiliates, and only under a WDH brand label, products that are covered by one or more of the Cochlear Licensed Patents, restricted solely to the Field of Use defined in Article 2.1. There is no right to sublicense or assign this license.

(*Id.*)

Article 4.2 of the 2009 License requires Cochlear to give WDH notice of recently issued or published patents or applications annually on September 1 (the "Annual Option Date"). (*Id.*) This notice is made by way of a list of patents and applications (the "Cochlear Update List"). (*Id.*) Upon receiving notice on the Annual Option Date, WDH has an opportunity to take a license of up to two of the disclosed patents or applications within ninety days, pursuant to Article 4.4. (*Id.*) Specifically, Article 4.4 states:

> No later than ninety (90) days following receipt of the Cochlear Initial List [of patents and applications] or the then current Cochlear Update List, WDH will identify by written notice to cochlear up to two (2) patents or patent applications from any current or prior Cochlear Initial List or Cochlear Update List from which WDH would like to obtain the same licensing rights for the Patent Family of the identified patents or patent applications under the same terms and conditions as set forth in Article 2 of this Agreement. ("Selected Cochlear Patents"). The notice provided in accordance with this paragraph 4.3 or paragraph 5.3 is referred to as "Selection Notice."

(*Id.*)

On February 4, 2011, Derek Minihane, Cochlear's IP Strategy Head ("Minihane"), sent an e-mail to various representatives from Oticon attaching a list of patent families to which Cochlear offered WDH license rights pursuant to Article 4 of the 2009 License. (Courtney Decl. (ECF No. 37-3, Ex. 1).) That list included, *inter alia*, U.S. Published Patent App. 2009/023109, which is part of the same patent application family as the subsequently issued '807 Patent. (*Id.*)

On November 24, 2011, Christian Hauge, Oticon's Senior Direction ("Hauge"), sent a letter to Minihane electing two patent applications on behalf of Oticon of which to obtain licensing rights pursuant to Article 4.4 of the 2009 License. (ECF No. 37-2, Ex. 8). WDH selected U.S. Publication No. US20100286776 and U.S. Publication No. US20100298626. (*Id.*) U.S. Publication No. US20100286776 corresponds to U.S. Patent No. 8,787,607 (the "Andersson '607

Patent"), which was issued to Cochlear by the United States Patent and Trademark Office on July 22, 2014. (Popelka Decl. (ECF No. 38-1, Ex. N).) Notably, the Anderson '607 Patent incorporates the '807 Patent by reference, stating:

> Further features and capabilities of a bone conduction implant . . . may be found in the . . . U.S. Provisional Application No. 60/951,163, entitled "Bone Anchor Fixture for a Medical Prosthesis," filed Jul. 20, 2007 . . . which [is] hereby incorporated by reference herein for application of their teachings, conceptually and/or exactly, to the reduction/elimination of micro-leakage paths, and for the configurations of a percutaneous bone conduction implant disclosed therein.

(*Id.* at 11:52-64.)

U.S. Provisional Application No. 60/951,163 corresponds to the '807 Patent, thereby incorporating such patent into the Anderson '607 Patent. (ECF No. 1-1.)

The 2009 License also includes certain limiting language, specifically Articles 9.3 and 13.3. Article 9.3 states that "[a]ll rights, including all intellectual property rights in any improvement to technology listed under this Agreement shall be owned by the Party making the improvement" and further stating that no license right to an "improvement" is granted "except as may occur through the procedures of Article 4 or Article 5." (ECF No. 37-2, Ex. 7.) Article 13.3 states that nothing in the 2009 License "shall constitute a license for any Party to utilize in the marketing of its products, the trademarks, trade names, any other intellectual property rights other than the Licensed Patents or Supplemental Licensed Patents." (*Id.*)

IV. DECISION

"A plaintiff seeking a preliminary injunction must establish that he is [1] likely to succeed on the merits, [2] that he [or she] is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his [or her] favor, and [4] that an injunction is in the public interest." *Ferring*, 765 F.3d at 210 (quoting *Winter*, 555 U.S. at 20). For the reasons set

forth below, the court finds, Cochlear has not met the significant threshold for obtaining a preliminary injunction, and as such, Cochlear's Motion for a Preliminary Injunction is denied.

A. Likelihood of Success on the Merits

i. Analysis of the Ponto BHX Implant

A party moving for a preliminary injunction has the burden to prove its likelihood of success on the merits of the case. *Ferring*, 765 F.3d at 210 (citing *Opticians Ass'n of Am.*, 920 F.2d at 192). A party proves a likelihood of success on the merits by demonstrating a "reasonable *probability* of eventual success in the litigation." *South Camden Citizens in Action v. N.J. Dep't of Envt'l Prot.*, 274 F.3d 771, 777 (3d Cir. 2001) (emphasis added). Specifically, in patent cases, a patentee "must show that, in light of the presumptions and burdens applicable at trial, it will likely prove that [the accused infringer] infringe[d] the asserted claims . . . and that the patent will likely withstand [any] challenges to its validity." *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1365 (Fed. Cir. 2002). Cochlear has not demonstrated a likelihood of success on the merits.

Pursuant to 35 U.S.C. § 271(a), "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." The court's infringement analysis involves a two-step process. *Tate*, 279 F.3d at 1365. The court "first construes the scope of the asserted claims and then compares the accused device to the properly construed claims to determine whether each and every limitation of a claim is present, either literally or equivalently, in the accused device." *Id.* (citing *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001)). Construing the scope of the asserted claim is generally an issue of law for the court, whereas comparing the patented product with the product alleged to be infringing is

generally a question of fact. *See Oakley, Inc. v. Sunglass Hut, Inc.*, 316 F.3d 1331, 1339 (Fed. Cir. 2003).

Cochlear asserts that Oticon's Ponto BHX Implant infringes claims 1-12, 14, 16-17, 25, 28, 33-35, 47-41, and 45-47 of the '807 Patent. (ECF No. 3-1 at 16.) In support of this argument, Cochlear points only to the Declaration of Mark E. Rentschler, Ph.D., who opines that, based on his analysis, Oticon's Ponto BHX Implant infringes the '807 Patent. (ECF No. 3-5 ¶ 33.) In support of his conclusion, Dr. Rentschler asserts only that the Ponto BHX Implant is threaded, includes a flange that serves as a stop, and includes an "annular groove" between the flange and the threads, similar to that featured in the '807 Patent. (ECF No. 3-5 ¶ 30.) Dr. Rentschler further notes the Ponto BHX Implant "includes laser-ablated surfaces that increase the roughness of the surfaces," however, there is no contention that the Baha Connect features such technologies. (ECF No. 3-5 ¶ 31.)

Oticon rebuts Cochlear's claim with a Declaration from Gerald R. Popelka, Ph.D. (ECF No. 38.) Both independent claims 1 and 8 of the '807 Patent focus on the circumferential groove of the Baha Connect, which Cochlear claims is present in the Ponto BHX Implant. (ECF No. 1-1.) As is apparent from the '807 Patent, the circumferential groove of the Baha Connect (labeled as 117) is structurally distinct from the screw threads (labeled as 108), which it separates from the flange. (ECF No. 1-1, fig. 2.) The fact that the circumferential groove is separate and distinct from the screw threads is further made evident by the fact that the '807 Patent identifies the circumferential groove as being on the "threaded side" of the implant, but notes it as an "additional element" to the "screw thread apparatus" in claim 1 and the "threaded tapered portion" in claim 8. (ECF No. 1-1 at 8.)

In analyzing patents, courts interpret separate claim terms to be distinct claim components.

See Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (holding that "[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not"); *see also Pause Tech., LLC v. TiVo, Inc.*, 419 F.3d 1326, 1334 (Fed. Cir. 2005) ("In construing claims . . . we must give each claim term the respect that it is due"); *see also Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1995). Accordingly, the circumferential groove of the '807 Patent should be interpreted as separate and distinct from the screw threads.

The text of the '807 Patent further confirms that the circumferential groove is separate from the screw thread as it specifically draws a distinction between the two and highlights the differences between them, stating:

> Circumferentially oriented grooves **117** may extend completely or partly around the periphery of the main body . . . . As an alternative, the grooves may be formed as a screw thread **108**, but having a[n] inner diameter **128** that is greater than the inner diameter **124** of the main screw thread **108**, so that the height of the [circumferential] grooves **117** would be only approximately 1/3 or less of the height **134** of main screw thread **108** . . . . In one embodiment, the extension of the second wide diameter portion **102C** in the longitudinal direction of the fixture is about 15-25% of the total height of the fixture.

(ECF No. 1-1 at 5:15-27.)

When examining the Ponto BHX Implant in light of the '807 Patent's explanation and definition of a circumferential groove, it is evident that the Ponto BHX Implant lacks such a feature. The Ponto BHX Implant has only one single grooved region, analogous to the screw threads of the Baha Connect, and lacks a distinct grooved region separating the threads from the flange. (ECF No. 38 ¶¶ 81-90.) Accordingly, when "constru[ing] the scope of the asserted claims and then compar[ing] the [Ponto BHX Implant] to the [Baha Connect]" the claims alleged to be infringed are not present in the Ponto BHX Implant. *Tate*, 279 F.3d at 1365. As such, Cochlear

has not demonstrated that Oticon's sale of the Ponto BHX Implant runs afoul of 35 U.S.C. § 271(a) and this Court is not satisfied that Cochlear has established a reasonable likelihood of success on the merits.

Moreover, even if Cochlear had demonstrated that Oticon's Ponto BHX Implant did contain "every limitation" of Cochlear's '807 Patent, such would still be insufficient to determine that Cochlear has demonstrated a likelihood of success on the merits, as Oticon has raised prior art and licensing defenses.

ii. The Prior Art

The merits of the case are called into question by the similarities between the '807 Patent and two prior arts: United States Patent No. 7,074,222, "Anchoring Element," issued to Patrik Westerkull on July 11, 2006 (the "Westerkull Patent") (ECF No. 38-1, Ex. H), and United States Patent No. 8,377,106, "Implant and an Implant Member," issued to Rickard Brånemark on February 19, 2013 (the "Brånemark Patent"). (ECF No. 38-1, Ex. I). Both of these patents undoubtedly pre-date the '807 Patent.

Although the Federal Circuit has made "clear that an accused infringer cannot defeat a claim of literal infringement or establish invalidity merely by pointing to similarities between an accused product and a prior art," this does not "preclude a litigant from arguing that if a claim term must be broadly interpreted to read on an accused device, then this same broad construction will read on the prior art." *01 Communique Laboratory, Inc v. Citrix Sys., Inc.*, 889 F.3d 735, 742 (Fed. Cir. 2018) (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1380 (Fed. Cir. 2007)). However, "when an accused product and the prior art are closely aligned, it takes exceptional linguistic dexterity to simultaneously establish infringement and evade invalidity." *01 Communique*, 889 F.3d at 742-43; *see also Tate*, 279 F.3d at 1367 (holding that "[w]here an

accused infringer is clearly practicing only that which was in the prior art, and nothing more, and the patentee's proffered construction reads on the accused device, meeting [the] burden of [establishing invalidity] should not prove difficult").

The Westerkull Patent features an upper flange that rests against the bone, threads of a single diameter towards the far end of the device, and a "channel" separating the flange from the threads. (ECF No. 38-1, Ex. H.) The Westerkull Patent claims an implant highly similar to the Ponto BHX Implant and like the Ponto BHX Implant, the Westerkull Patent describes a tapered, threaded skull implant device with a *single* threaded section of a constant pitch. (*Id.*) Unlike the Baha Connect, neither the Westerkull Patent nor the Ponto BHX Implant feature a groove separating the threads from the flange of a differing diameter, as does the '807 Patent's circumferential groove.

Like the Westerkull Patent, the Brånemark Patent features a flange at its top end, a threaded and roughened lower section to enhance bone integration, and a gap region between the threads and the flange. (ECF No. 38-1, Ex. I.) As with the Ponto BHX Implant, the Brånemark Patent lacks a distinctive threaded or grooved section separating the threads from the flange. (*Id.*) Moreover, the Brånemark Patent features a roughening surface of the threads meant to enhance osseointegration, which the '807 Patent also features. (*Id.*) Although this Court does not determine that the Westerkull Patent or the Brånemark Patent should render the '807 Patent invalid pursuant to the prior art principle clearly developed by the Federal Circuit, the similarities between these prior arts and the Ponto BHX Implant significantly undercut Cochlear's argument such that Cochlear has failed to demonstrate a likelihood of success on the merits.[1]

[1] Additionally, the Court does not find Cochlear's oral argument contention persuasive that the products contained in the Westerkull and Brånemark Patents are used only for dental procedures.

iii. The 2009 License

Even if this Court had found that the Ponto BHX Implant did infringe upon the '807 Patent, the 2009 License between WDH and Cochlear licensed Oticon to sell such a product in the United States. Pursuant to Article 4.4, upon receiving notice on the Annual Option Date, WDH had the opportunity to take a license of up to two of the disclosed patents or applications within ninety days. (ECF No. 37-2, Ex. 7.) On February 4, 2011, Minihane sent an e-mail to Oticon representatives attaching a list of patent families to which Cochlear offered WDH licensing rights pursuant to 2009 License. (ECF No 37-3, Ex. 1.) The list included U.S. Published Patent App. 2009/023109, which is part of the same patent application family as the issued '807 Patent. Thereafter, on November 24, 2011, WDH selected, via a letter from Hauge to Minihane, U.S. Publication No. US20100286776 and U.S. Publication No. US20100298626. (ECF No. 37-2, Ex. 8.) U.S. Publication No. US20100286776 corresponds to the Andersson '607 Patent, which incorporated the '807 Patent by reference. (ECF No. 38-1, Ex. N.) Accordingly, Oticon elected the '807 Patent in its November 2011 letter, and as such, it has a right to be free from suit for infringing upon the '807 Patent.

Cochlear contends that Swedish law applies to the interpretation of the 2009 License, and that Oticon's interpretation is unreasonable under Swedish law. (ECF No. 43 at 9.) Specifically, Cochlear asserts that "Oticon argues that use of one licensed Cochlear patent in a product, makes that product licensed as to all of Cochlear's intellectual property." (*Id.*) This is a misrepresentation of Oticon's argument concerning the 2009 License, which fails to address Oticon's election of the Andersson '607 Patent in its November 24, 2011 letter. Moreover, in support of its contention that

Oticon's interpretation is unreasonable under Swedish law, Cochlear cites only to a Declaration from Bengt Domeji, a Professor of Private Law at Uppsala University, Sweden, which stated:

> A claim that a license to one patent should entail a license to all patents held by the licensor for a certain product would in my opinion have to be supported by unequivocal wording to that effect in the contract and perhaps be underpinned by additional information concerning party intentions at the time of the agreement or subsequent performance of the contract. It would have been facile for the parties to explain such an unlikely intention more clearly, if that truly was the agreement.

(Bengt Decl. (ECF No. 43-1 ¶ 20).)

However, Oticon does not assert that a claim to a license to one patent entails a license to *all* patents held by the licensor. Rather, Oticon explicitly elected licensing to the '807 Patent, pursuant to Article 4.4 of the 2009 License, via the November 24, 2011 letter. Thus, even if the Ponto BHX Implant had infringed upon the '807 Patent, there is a legitimate question as to whether Oticon had license to do so, further underscoring Cochlear's argument that it has demonstrated a likelihood of success on the merits.

B. Irreparable Harm

Even if Cochlear demonstrated a likelihood of success on the merits, it has still failed to demonstrate that it would suffer irreparable harm absent a preliminary injunction. In order for a movant to be entitled to a preliminary injunction, such movant bears the burden of demonstrating that it is likely to suffer irreparable harm in the absence of such relief. *Ferring*, 765 F.3d at 210. "The basis of injunctive relief in the federal courts has always been irreparable harm and inadequacy of legal remedies." *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 506-07 (1959). To demonstrate irreparable harm in a patent infringement action, "a patentee must establish both of the following: 1) that absent an injunction, it will suffer irreparable harm, and 2) that a sufficiently strong causal nexus relates the alleged harm to the alleged infringement." *Apple, Inc.*

v. Samsung Elecs. Co., Ltd., 695 F.3d 1370, 1374 (Fed. Cir. 2012). A preliminary injunction seeks to make the movant whole for "harms that no damages payment, however great, could address," such as "[p]rice erosion, loss of goodwill, damages to reputation, and loss of business opportunities." *Celcis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012). Mere speculation may not suffice for the finding of irreparable harm. *See Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991).

Even had Cochlear demonstrated a likelihood of success on the merits, it has still failed to demonstrate that it would suffer irreparable harm absent a preliminary injunction. Cochlear asserts that Oticon's promotion of its implant will likely lead to the loss of potential life-long clients, and that such damages are "difficult, if not impossible, to quantify." (ECF No. 3-1 at 19.) This Court is not persuaded that Cochlear's simple loss of business is non-compensable with money damages. Cochlear merely makes the bald assertion that it would suffer irreparable harm absent the preliminary injunction while providing absolutely no evidence to that effect. Federal courts have made abundantly clear that a finding of irreparable harm must be rooted in evidence and not merely speculation. *See Winter*, 555 U.S. at 22; *see also Nutrition 21*, 930 F.2d at 871. Furthermore, Cochlear admitted that the Ponto BHX Implant is capable of use with both the Ponto sound processor and Cochlear's Baha sound processor. (ECF No. 3-1 at 3-4.)

Cochlear cites *Robert Bosch v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1153 (Fed. Cir. 2011) for the proposition that courts are "more likely to grant an injunction in two-player markets where the parties are direct competitors." (ECF No. 3-1 at 20.) However, Cochlear's argument is undercut by the fact that it offered licensing of its products to WDH, as federal courts have held that past licensing on non-exclusive terms weighs against a finding of irreparable harm. *See High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1556-57 (Fed. Cir. 1995).

Therefore, this Court finds that Cochlear has not demonstrated that it would suffer irreparable harm absent a preliminary injunction.

C. Balance of the Equities

The third prong of the preliminary injunction inquiry requires the movant to demonstrate that the balance of equities tips in its favor in granting the injunction. *Ferring*, 765 F.3d at 210. Cochlear asserts that the balance of hardships decidedly favors the grant of injunctive relief because it will be irreparably harmed if Oticon continues to promote and sell the Ponto BHX Implant since Oticon "could simply return to selling the implant it offered prior to the BHX implant." (ECF No. 3-1 at 20.) Oticon counters that the balance of hardships warrants a denial of the motion as there is no evidence demonstrating price erosion or irreparable harm to Cochlear's reputation. (ECF No. 37 at 33.)

As discussed above, Cochlear has failed to demonstrate that it would suffer irreparable harm absent the granting of the preliminary injunction. Cochlear has produced absolutely no evidence tending to prove any damage to its reputation, nor other non-compensable damages, as a result of Oticon's sale of its Ponto BHX Implant. Rather, the preliminary injunction would merely deprive Oticon of the ability to sell its Ponto BHX Implant while Cochlear has failed to demonstrate a likelihood of success on the merits. Moreover, the fact that Oticon manufactures other products that it could sell in the United States during the pendency of the trial is immaterial to this motion for a preliminary injunction.

D. Public Interest

The final prong of the preliminary injunction inquiry requires the movant to demonstrate that it is within the public interest to grant the injunction. *Ferring*, 765 F.3d at 210. Cochlear has failed to make this showing. In support of its contention that the public interest favors granting the

injunction, Cochlear cites several decisions noting that the importance of enforceable patent rights. (ECF No. 3-1 at 21.) However, this Court has determined that Cochlear has not demonstrated a likelihood of success on the merits and therefore there is no indication that the '807 Patent may be enforced against Oticon's Ponto BHX Implant. On the contrary, the public interest would be best served by allowing the sale of the Oticon implant and thereby promote patient choice during the pendency of the trial and until a decision is reached on the merits.

V. CONCLUSION

For the reasons set forth above, Cochlear's motion for a preliminary injunction is **DENIED**.

Date: October 26, 2018

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE